REMARKS

Attached hereto is an Appendix showing the changes made to claims 18 and 29, as amended.

Applicants submit that the objection of claim 18 is obviated by the above amendment, wherein the extra "at" is removed. The nature of the amendment is typographical and therefore no new matter is introduced. The entry of the amendment is therefore respectfully requested.

The rejection of claims 17-20, 22, and 24-29 under 35 USC § 112, second paragraph, as being indefinite is respectfully traversed.

Specifically, the examiner contends that in claim 17, phrase "effective amount of cytokine or co-stimulatory molecule" is unclear. The definiteness of the claim language must not be analyzed in vacuum but in light of the content of the specification and teachings of the prior art to one skilled in the art. See In re Moore, 58 CCPA 1042, 439 F.2d 1232, 169 USPQ 236 (1971). Like in Watson, wherein the term "germicide" in the phrase "effective amount of germicide" was construed to indicate its effect sought to be produced, i.e. germicidal activity, the term "co-stimulatory" in the phrase "effective amount of cytokine or co-stimulatory molecule" in the present application clearly defines that the effect sought is "stimulatory." In re Watson, 517 F.2d 465, 186 USPQ 11 (CCPA 1975). Moreover, in the specification, on page 11, lines 27-30, and page 12 lines 1-4, applicants give specific examples concerning the amount of an exemplary co-stimulatory molecule, IL-2, that can be used *in vitro*. Further, on page 13, first full paragraph, applicants describe an example, wherein a therapeutic application using an exemplary amount of co-stimulatory molecule, IL-2, *in vivo,* is outlined. In addition, applicants further describe on page 11, lines 3-7, that the "cytokine or co-stimulatory molecule" may be used as "biologic adjuvants." The term "adjuvant" means "serving to aid or contribute" (http://www.m-w.com/cgi-bin/dictionary) , or "in immunology, a nonspecific stimulator of the immune response" (http://www.ndif.org/Terms/adjuvant.html).

In light of the above, applicants submit that those skilled in the art will be able to determine from the disclosure, including the examples, what an "effective amount of cytokine or co-stimulatory molecule" is with a reasonable degree of precision and particularity. Id. Therefore, applicants respectfully request that the rejection of claim 17 be withdrawn.

The examiner also argued that the phrase "additional PSA" in claims 18 and 19 is unclear. Applicants submit that the phrase "additional PSA" is clearly exemplified on page 6, second to last paragraph and the paragraph bridging pages 6 and 7. Further, Table 1 on page 27 shows exemplary doses of additional immunogen in consecutive immunizations. In light of these examples and the paragraph bridging pages 10 and 11, a skilled artisan having read the specification, would know that after the first immunization a booster dose with additional PSA can be administered and has guidance with a reasonable degree of precision and particularity what the "additional PSA" means. In light of the above, applicants submit that those skilled in the art will be able to determine from the disclosure, including the examples, what an "additional PSA" is. Therefore, applicants respectfully request that the rejection of claims 18 and 19 be withdrawn.

The examiner further contends that the phrase "T-cell eliciting epitope thereof" is indefinite. Applicants submit that the phrase "T-cell eliciting epitope thereof" used in claims 17-20, 22, and 24-29, is defined in the specification so as to enable one skilled in the art to understand, with a reasonable degree of precision and particularity what is claimed. Specifically, applicants teach a method of establishing whether an epitope elicits a T-cell response on p. 11, under title "Generation of Cytotoxic T-Cells" and p. 12 under "Epitope Mapping" and Example 2 (pp. 32-33). Applicants refer to routine methods known to one skilled in the art of immunology and present examples of useful epitopes. In light of the above, applicants submit that those skilled in the art will be able to determine from the disclosure, including the examples, with a reasonable degree of precision and particularity what a "T-cell eliciting epitope thereof" is. Therefore, applicants respectfully request that the rejection of claims 17-20, 22, and 24-29 be withdrawn.

Examiner correctly pointed out that the term "pox vector" in claim 29 lacked antecedent basis in claim 18. In claim 29, applicants had inadvertently referred back to claim 18. Applicants submit an amended claim 29, which refers to claim 19, wherein the term "pox virus vector" is used. Applicants have further amended the term "pox vector" to "pox virus vector." The term "virus" is added not as a limitation but rather to give an exact antecedent basis of the term in claim 19. The amendment is supported throughout the specification and particularly on page 11, lines 3-7, and thus does not introduce new matter, and its entry is respectfully requested.

Therefore, in light of the amendment applicants and the discussion above, applicants submit that the rejection of claims 17-20, 22, and 24-29 under 35 USC § 112, second paragraph, should be withdrawn.

The statutory double patenting rejection of claims 17-20, 22, and 24-25 is respectfully traversed. Unlike in the U.S. Patent No. 6,165,460, the present claims are directed to "[a] method for generating an immune response to prostate-specific antigen (PSA) in a host, comprising, contacting the host with a sufficient amount of PSA or a cytotoxic T-cell eliciting epitope thereof and an effective amount of a cytokine or co-stimulatory molecule." Emphasis added. Claims 4-6, 8, and 11-13 in the U.S. Patent No. 6,165,460 do not recite "and an effective amount of a cytokine or co-stimulatory molecule." Therefore, because the claims 17-20, 22, and 24-29 here are not the same as claims 4-6, 8, and 11-13 in the U.S. Patent No. 6,165,460, applicants respectfully submit that the statutory double patenting rejection is improper. Therefore, applicants request that the double patenting rejection should be withdrawn.

The rejection of claims 17 and 26 under 35 USC § 102(b) as anticipated over Bronte et al. (J. Immunol., 1995 May 15; 154(10):5282-92) ("Bronte") is respectfully traversed. Bronte generally discusses tumor specific antigens (TAA), and contrary to the examiner's contention, Bronte does not disclose or even suggest using prostate specific antigen, PSA. Bronte's examples describe use of a "model TAA" which is described as consisting of amino acids 876-884 of the β-gal (see, e.g., page 5283, second column, under heading "Peptides"). Because Bronte does not disclose all the elements of the present invention, Bronte cannot anticipate the

present invention. Consequently, applicants request the rejection over Bronte should be withdrawn.

The rejection of claims 17-20, 22, 24 and 25 under 35 USC § 103(a) over Correale et al. (J. Immunol. 1998 Sep. 15; 161(6):3186-94)("Correale") in view of Bronte and Hodge et al. (Int. J. Cancer, 1995, Oct 9;63(2):231-37)("Hodge") is respectfully traversed.

As properly noted in the papers accompanying the application upon filing, the present application is a continuation application of the U.S. Serial No. 08/500,306, now a U.S. Patent No. 6,165,460, filed July 10, 1995. In issuing this rejection, the examiner has improperly cited art which was published after the effective filing date of the present application, i.e. Correale, published in September 1998 and Hodge, published in October 1995. Therefore, these references cannot contribute to the obviousness of the present invention. Further, as discussed above, Bronte neither teaches nor suggests the use of PSA. Therefore, the rejection under these references is improper and should be withdrawn.

In view of the foregoing, applicant respectfully submits that all claims are in condition for allowance. Early and favorable action is requested.

In the event that any additional fees are required, the PTO is authorized to charge our deposit account No. 50-0850.

Respectfully submitted,

Date: 12/27/02

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APPENDIX

The changes made by the amendments to the specification and the claims are shown below with insertions being underlined and deletions being bracketed.

18. (AMENDED) The method of claim 17, further comprising at [at] least one periodic interval thereafter contacting the host with additional PSA or a cytotoxic T-cell eliciting epitope thereof.

29. (AMENDED) The method of claim [18]19, wherein the pox virus vector further contains a DNA encoding a cytokine or a co-stimulatory molecule.